

ISSUE HIGHLIGHTS



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Safety First!

As professionals engaged with all stages of pharmacology, we are heavily invested in efforts to promote robust science and interpretation of evidence regarding therapeutics to both maximise benefit and minimise harms of any prescribed therapeutic. Regulatory bodies perform a crucial service in evidence interpretation and pharmacovigilance, yet the traditional timelines of regulatory processes have been challenged by urgent need in the current pandemic context and there has often been uncertainty in a period before robust evidence can be gathered. The irony of initial concerns regarding corticosteroid use in COVID-19 coupled with later data demonstrating robust survival benefit from dexamethasone is a lesson best remembered.

This issue of BJCP has a timely emphasis on regulatory science, starting from the first editorial and commentary. With increasing intersection of regulatory bodies and external politics as the COVID-19 pandemic continue to occupy central stage internationally, we can all benefit from returning to first principles.

Regulatory science: Regulation is too important to leave it to the regulators

Hubert G. Leufkens

DOI: [10.1111/bcp.13917](https://doi.org/10.1111/bcp.13917)

Effect of pharmaceutical regulatory policy on health impact

Jennifer H. Martin

DOI: [10.1111/bcp.14390](https://doi.org/10.1111/bcp.14390)

These initial articles are complemented by a French retrospective cohort study illustrating the dangers of off-label morphine prescription, an excellent example of the importance of adherence to regulatory endorsed prescribing.

Risk assessment of using off-label morphine sulfate in a population-based retrospective cohort of opioid-dependent patients

Célian Bertin, Jessica Delorme, Marie Riquelme, Hélène Peyrière, Georges Brousse, Alain Eschalier, Denis Ardid, Chouki Chenaf and Nicolas Authier

DOI: [10.1111/bcp.14082](https://doi.org/10.1111/bcp.14082)

In another example of dangers of inappropriate medication prescription, an Austrian prospective cohort study found that over a quarter of admissions for elderly patients identified as taking potentially inappropriate medication was attributable to the medication use.

Potentially inappropriate medication use and related hospital admissions in aged care residents: The impact of dementia

Tesfahun C. Eshetie, Greg Roberts, Tuan A. Nguyen, Marianne H. Gillam, Dorsa Maher and Lisa M. Kalisch Ellett

DOI: [10.1111/bcp.14345](https://doi.org/10.1111/bcp.14345)

An interesting retrospective Dutch study revealed that approximately a third of pregnant women have consistently used potentially harmful medication over the past 20 years. Notably, the current trend is particularly significant in ethnic minorities and in women with chronic medical conditions. While the first of these groups may find an appropriate decrease in potentially risky medication use with improved health education access initiatives, women with chronic medical conditions (along with advancing age) are increasingly seen in pregnancy and appropriate use of medication may include potential risk that is, on balance, outweighed by benefit.,

Dutch trends in the use of potentially harmful medication during pregnancy

Eline Houben, Bernke te Winkel, Eric A. P. Steegers and Ron M. C. Herings

DOI: [10.1111/bcp.14341](https://doi.org/10.1111/bcp.14341)

A randomised cross-over study from France highlights the significant benefit of pharmacist intervention in hospital to reduce drug related and severe iatrogenic problems.

Effectiveness of a multicomponent pharmacist intervention at hospital discharge for drug-related problems: A cluster randomised cross-over trial

Xavier Pourrat, Clémence Leyrat, Benoît Allenet, Brigitte Bouzige, Armelle Develay, Martial Fraysse, Valérie Garnier, Jean-Michel Halimi, Clarisse Roux-Marson and Bruno Giraudeau

DOI: [10.1111/bcp.14349](https://doi.org/10.1111/bcp.14349)

A further important contribution on the topic of pharmacovigilance in this issue comes from Modgill et al., who refute the so called 'Webber effect', which describes peak adverse drug reports at two years post market authorization with subsequent decline in AR reports despite increasing use, within specialty care medicines.

Reporting rates of adverse reactions to specialty care medicines exhibit a direct positive correlation with patient exposure: A lack of evidence for the Weber effect

Vikas Modgill, Léa Dormegny and David J. Lewis

DOI: [10.1111/bcp.14342](https://doi.org/10.1111/bcp.14342)

In terms of post-marketing surveillance, DOACs remain a topic of interest. Two studies in this issue consider DOAC safety. The first, an Italian study, is a multicentre prospective cohort study that examined annual decline in eGFR, comparing DOACs used for nonvalvular AF to patient prescribed a VKA for the same indication. They found that there was less decline in renal function in those patients taking DOACs rather than VKAs. The second, a French, study, was interested in comparing bleed risk from real world data of patients taking DOACs vs VKAs for any indication. They found a significantly reduced risk of intracranial or other major bleed with DOACs as compared with VKAs, though no difference in risk of major gastrointestinal bleed.

Association of different oral anticoagulants use with renal function worsening in patients with atrial fibrillation: A multicentre cohort study

Daniele Pastori, Evaristo Ettorre, Gregory Y.H. Lip, Angela Sciacqua, Francesco Perticone, Francesco Melillo, Cosmo Godino, Rossella Marcucci, Martina Berteotti, Francesco Violi, Pasquale Pignatelli, Mirella Saliola, Danilo Menichelli, Marco Antonio Casciaro and Vito Menafra

DOI: [10.1111/bcp.14350](https://doi.org/10.1111/bcp.14350)

Major bleeding risk associated with oral anticoagulant in real clinical practice. A multicentre 3-year period population-based prospective cohort study

Jacques Bouget, Frédéric Balusson, Maxime Maignan, Laure Pavageau, Pierre-Marie Roy, Karine Lacut, Lucie-Marie Scalteux, Emmanuel Nowak and Emmanuel Oger

DOI: [10.1111/bcp.14362](https://doi.org/10.1111/bcp.14362)

In a forward looking EMA guideline article, a model is proposed with recommendations to invest in regulatory science innovation within Europe to allow regulatory science to keep up with innovation over the next 5–10 years. This appears critical!

Regulatory Science and Innovation Programme for Europe (ReSciPE): A proposed model

Philip A. Hines, Richard H. Guy, Angela Brand, Anthony J. Humphreys and Marisa Papalucia-Amati

DOI: [10.1111/bcp.14099](https://doi.org/10.1111/bcp.14099)

There are also many other fantastic contributions in this issue of BJCP and we recommend a cover to cover read!